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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA INT'L FEDERAL EXPRESS

May 7, 2001

Our Reference: 2954515

Jojo Huang, President
Polar International
1026 Cabras Highway
F-2 Casamar
Piti, Guam 96925

WARNING LETTER

Dear Mr. Huang:

On April 10 and 14, 2001, we inspected your seafood firm to determine your compliance with FDA's Seafood HACCP regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deviations. These deviations cause your fresh tuna and marlin to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the deficiencies on a Form FDA 483 and discussed them with you at the conclusion of the inspection. The deviations are as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan to control the food safety hazard of histamine formation as a result of time/temperature abuse in fresh tuna and marlin received directly from the harvest vessel.
2. You must adequately monitor and document sanitation conditions and practices, to comply with 21 CFR 123.11(b) and (c). However, your firm did not monitor and maintain records related to the following areas of sanitation to ensure control:
 - a) Safety of water;

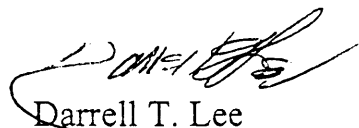
- b) Condition and cleanliness of food contact surfaces;
- c) Prevention of cross-contamination;
- d) Maintenance of hand washing, hand sanitizing, and toilet facilities;
- e) Protection of food and food contact surfaces from adulterants;
- f) Proper labeling and storage of toxic compounds;
- g) Control of employee health conditions; and
- h) Exclusion of pests from the processing area.

We acknowledge your response of April 24, 2001 to the inspectional observations presented to you at the close of the inspection. The letter has been appended to your company file, and we will verify the effectiveness and implementation of your HACCP system at the next inspection. We may take regulatory action without further notice if you fail to implement your HACCP plan as proposed. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your seafood firm operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,



Darrell T. Lee
Acting Director
San Francisco District